



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

March 23, 2020

Jennifer M. Richardt  
President  
Earth Laboratories Inc.  
1101 East Diamond Ave.  
Evansville, IN 47711

Subject: Label Amendment: Adding the Emerging Viral Pathogens Claim  
Product Name: Peroxy HDOX  
EPA Registration Number: 84198-1  
Application Date: 02/27/2020  
Decision Number: 560824

Dear Ms. Richart:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Because you have opted to add statements pertaining to emerging viral pathogens to your label as described in the August 19, 2016, Guidance to Registrants: Process For Making Claims Against Emerging Viral Pathogens Not On EPA-Registered Disinfectant Labels ("Guidance"), [https://www.epa.gov/sites/production/files/2016-09/documents/emerging\\_viral\\_pathogen\\_program\\_guidance\\_final\\_8\\_19\\_16\\_001\\_0.pdf](https://www.epa.gov/sites/production/files/2016-09/documents/emerging_viral_pathogen_program_guidance_final_8_19_16_001_0.pdf), you are subject to the following additional terms of registration:

1. You may make statements pertaining to emerging viral pathogens only through the following communications outlets: technical literature distributed exclusively to health care facilities, physicians, nurses and public health officials, "1-800" consumer information services, social media sites and company websites (non-label related). These statements shall not appear on marketed (final print) product labels.

2. Your statements pertaining to emerging viral pathogens must adhere to the format approved on the Agency-accepted master label.
3. You may make statements pertaining to emerging viral pathogens only upon a disease outbreak that meets all the following criteria:
  - a. The causative organism must be a virus that causes an infectious disease that has appeared in a human or animal population in the U.S. for the first time, or that may have existed previously but is rapidly increasing in incidence or geographic range.
    - i. For human disease, the outbreak is listed in one of the following Centers for Disease Control (CDC) publications:
      - A. CDC Current Outbreak List for “U.S. Based Outbreaks” ([www.cdc.gov/outbreaks](http://www.cdc.gov/outbreaks)),
      - B. CDC Current Outbreak List for “Outbreaks Affecting International Travelers” with an “Alert” or “Advisory” classification ([www.cdc.gov/outbreaks](http://www.cdc.gov/outbreaks)) (also released through the CDC’s Health Alert Network (HAN) notification process)
      - C. Healthcare-Associated Infections (HAIs) Outbreaks and Patient Notifications page ([www.cdc.gov/hai/outbreaks](http://www.cdc.gov/hai/outbreaks))
    - ii. For animal disease, the outbreak is identified as an infectious disease outbreak in animals within the U.S. on the World Organization for Animal Health (OIE) Weekly Disease Information page ([www.oie.int/wahis\\_2/public/wahid.php/Diseaseinformation/WI](http://www.oie.int/wahis_2/public/wahid.php/Diseaseinformation/WI)).
  - A. The CDC or OIE has identified the taxonomy, including the viral family and/or species, of the pathogen and provides notice to the public of the identity of the emerging virus that is responsible for an infectious disease outbreak. Based on the taxonomy of the outbreak pathogen identified by the CDC or OEI, the pathogen's viral subgroup are large non-enveloped and enveloped.
  - B. The virus can be transmitted via environmental surfaces (non-vector transmission), and environmental surface disinfection has been recommended by the CDC, OIE or EPA to control the spread of the pathogen.
4. You may begin communicating statements pertaining to emerging viral pathogens only upon CDC or OIE’s publication per term 3.a. of an outbreak of an emerging viral pathogen meeting all of the criteria of term 3. You must cease and remove all such non-label communications intended for consumers no later than 24 months after the original publication of the outbreak per term 3.a., unless the Agency issue written guidance to the contrary due to continued public health concerns. The emerging pathogen claim language may remain on the master label.

5. Terms from points 1 through 4 above shall become immediately void and ineffective if registration for use against Norovirus (Feline Calicivirus) is suspended or cancelled or no longer meets the criteria for a disinfectant claim (see EPA Product Performance Test Guideline 810.2200). In addition, terms B.1 through B.4 above shall become immediately void and ineffective upon your receipt of evidence of ineffectiveness against any pathogen in a less-resistant Spaulding category.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, you may contact the disinfectantslist via email at [disinfectantslist@epa.gov](mailto:disinfectantslist@epa.gov).

Sincerely,



John Hebert, Chief  
Regulatory Management Branch 1  
Antimicrobials Division (7510P)  
Office of Pesticide Programs

Enclosure: Stamped Label

{Note to Agency: Text appearing in parenthesis or brackets is done to show optional text}.  
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## PEROXY HDOX

[MULTI-SURFACE] [ONE-STEP] [DISINFECTANT]  
[SANITIZER] - [CLEANER] - [DEODORIZER]  
[†VIRUCIDAL] - [FUNGICIDAL]

[Peroxy HDOX is a multi-purpose, germicidal, †virucidal, and fungicidal cleaner and deodorizer that disinfects or sanitizes (non-food contact surfaces), cleans, and removes malodors for hard, non-porous, inanimate surfaces]

### ACTIVE INGREDIENT:

Hydrogen Peroxide.....6.70%

OTHER INGREDIENTS:.....93.30%

**TOTAL:**.....100.00%



**KEEP OUT OF REACH OF CHILDREN**

### WARNING

See additional precautionary statements on [back] [side] [left] [right] [panel] of label [below].

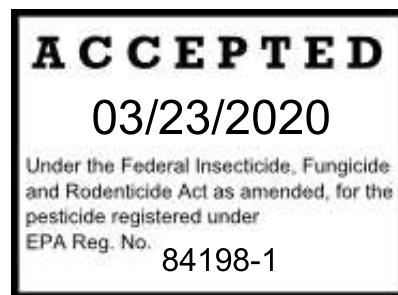
EPA Reg. No. 84198-1  
EPA Est. No. 84198-IN-001

Net Contents:

{Manufactured by:}  
Earth Laboratories, Inc.  
1101 E. Diamond Avenue  
Evansville, IN 47711  
(866) 203.0535  
www.earthlaboratories.com

[PRODUCT OF THE USA]

Expiration Date: [may appear on label or container]



### **Recommended Use (Locations):**

Peroxy HDOX is a multipurpose germicidal, <sup>†</sup>virucidal, and fungicidal cleaner and deodorizer that disinfects or sanitizes, cleans, and removes malodors in one labor saving step. Recommended for use in, but not exclusive to:

<b>Hospitals</b>	<b>Schools</b>	<b>Airports</b>
<b>Nursing Homes</b>	<b>Universities</b>	<b>Tanning Salons</b>
<b>Health Care Settings</b>	<b>Gymnasiums</b>	<b>Retail Facilities</b>
<b>Hotels &amp; Motels</b>	<b>Locker Rooms</b>	<b>Warehouses</b>
<b>Cruise Ships</b>	<b>Restrooms</b>	<b>Commercial Facilities</b>
<b>Dormitory Rooms</b>	<b>Fitness Centers</b>	<b>Industrial Facilities</b>
<b>Temporary Housing</b>	<b>Day Care Centers</b>	<b>Public Forums</b>
<b>Households</b>	<b>Office Buildings</b>	<b>Auditoriums</b>
<b>Public Transportation</b>	<b>Casinos</b>	<b>Churches</b>
		<b>Supermarkets</b>

### **Recommended Use (Surfaces):**

Peroxy HDOX cleans, disinfects, is fungicidal, is <sup>†</sup>virucidal, or sanitizes the following hard nonporous, inanimate, non-food contact surfaces when used as directed. The following areas and surfaces represent, but are not all-inclusive of, typical habitats for the bacteria, virus, and/or fungi kill claims for this product:

<b>Floors, Walls, Ceilings</b>	<b>Plastic &amp; Metal Pipes</b>
<b>Windows, Glass, Mirrors</b>	<b>Quarry Tile, Natural Stone, Sealed Grout</b>
<b>Doors, Door Handles</b>	<b>Vinyl &amp; Plastic</b>
<b>Toilets<sup>1</sup> &amp; Urinals<sup>1</sup></b>	<b>Stainless Steel, Aluminum, Brass, Soft Metals</b>
<b>Sinks, Counter tops, Fixtures</b>	<b>Production &amp; Materials Handling Equipment</b>
<b>Tables, Chairs, Bed Frames</b>	<b>Office Equipment</b>
<b>Painted Surfaces</b>	<b>Fitness Equipment</b>
<b>Glazed Porcelain &amp; Ceramic</b>	
<b>Baked Enamel</b>	<b>[Metal Condensing Coils]</b>

This product when used as directed as a cleaner can be used on all surfaces not harmed by water.

<sup>1</sup> Non-water covered areas.

### **For Use as a Cleaner/Disinfectant/Fungicide/Virucide:**

**Disinfectant:** Peroxy HDOX, when [used as directed at] [diluted] [10 ounces of concentrate] [product] per gallon of water is effective against *Pseudomonas aeruginosa* [ATCC 15442], *Staphylococcus aureus* [ATCC 6538], *Salmonella enteric* [ATCC 10708], *Streptococcus pneumonia* [ATCC 6303], *Escherichia coli* [ATCC 11229], *Staphylococcus aureus* – MRSA [ATCC 33592], & Community Associated Methicillin *Staphylococcus aureus* CA-MRSA (USA 400) [NRS 123] in the presence of 200 ppm hard water, 5% soil load and a 10 minute contact time on hard non-porous inanimate surfaces.

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Peroxy HDOX, when [used as directed at] [diluted] [10 ounces of concentrate] [product] [per gallon of water] [used concentrated] is effective against Feline Calicivirus, and Norovirus in the presence of 200 ppm hard water, 5% soil load and a 5 minute contact time on hard non-porous inanimate surfaces.

**Fungicidal:** Peroxy HDOX, when [used as directed at] [diluted] [10 ounces of concentrate] [product] [per gallon of water] [used concentrated] is effective against Trichophyton mentagrophytes [ATCC 9533] in the presence of 200 ppm hard water, 5% soil load, and a 10 minute contact time on hard non-porous inanimate surfaces.

**†Virucidal:** Peroxy HDOX, when [used as directed at] [diluted] [10 ounces of concentrate] [product] [per gallon of water] [used concentrated] is effective against Influenza Type A (Hong Kong) [ATCC VR-544] and Respiratory syncytial virus (RSV) in the presence of 200 ppm hard water, 5% soil load and a 10 minute contact time on hard non-porous inanimate surfaces.

Kills HIV-1 [AIDS virus] [HTLV-III<sub>B</sub>] [when used as directed at] [5 ounces of concentrate] [product] [per gallon of water] [used concentrated] in the presence of 200 ppm hard water on hard non-porous inanimate surfaces with a 5 minute contact time.

**Sanitizing:** Peroxy HDOX, when [used as directed at] [diluted] [5 ounces of concentrate] [product] [per gallon of water] [used concentrated] is effective as a non-food contact sanitizer against Staphylococcus aureus [ATCC 6538] and Enterobacter aerogenes [ATCC 13048] in the presence of 200 ppm hard water, 5% soil load and a 5 minute contact time on hard non-porous inanimate surfaces.

## **PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

**WARNING:** Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Wear goggles or face shield when handling product concentrate such as when making use dilutions. Harmful if swallowed. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse. Causes moderate eye irritation. Avoid contact with eyes or clothing.

*{The following will be used only on labels with dilution instructions}*

Note: After Peroxy HDOX is diluted in accordance with the directions for use, safety glasses and goggles are not required. [Peroxy HDOX] [Product], after dilution in accordance with the directions for use, is non-irritating.

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## **FIRST AID**

**IF IN EYES:** Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Call a poison control center or doctor for treatment advice.

**IF SWALLOWED:** Call a poison control center or doctor immediately for treatment advice. Have a person sip a glass of water if able to swallow. Do not induce vomiting unless told to by a poison control center or doctor. Do not give anything to an unconscious person.

**IF ON SKIN OR CLOTHING:** Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

**IF INHALED:** Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment.

## **DIRECTIONS FOR USE**

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. This product is not for use on medical device surfaces.

**This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that [1] is introduced directly into the human body, either into or in contact with the blood stream or normally sterile areas of the body, or [2] contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.**

### **For Use as a Cleaner/Disinfectant/Fungicide/Virucide:**

Dilute 10 ounces of concentrate per gallon of water. Thoroughly wet hard non-porous inanimate surface with the use-solution. The use-solution can be applied with a coarse spray, cloth, mop, or by soaking. For sprayer applications use a coarse spray device 6-8 inches from the surface. Let use-solution remain on surface for a minimum of 10 minutes, wipe clean and allow to air dry. If unusually heavy soil deposits exist, pre-clean with Peroxy HDOX (as directed for use as a cleaner) prior to disinfecting. Replace mop bucket solution daily.

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Peroxy HDOX Kills HIV-1, Norovirus,[and][&] Feline Calicivirus when used as directed at 5 oz. of concentrate per gallon of water in the presence of 200 ppm hard water on hard, non-porous, inanimate surfaces with a 5 minute contact time.

**\*KILLS HIV ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS** in health care settings and other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood / body fluids, and in which the surfaces / objects likely to be soiled with blood / body fluids can be associated with the potential for transmission of Human Immunodeficiency Virus Type 1 [HIV-1] [associated with AIDS].

**SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 [AIDS Virus] OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS.**

**Personal Protection:** Disposable latex or vinyl gloves, gowns, face masks, or eye coverings as appropriate, must be worn during all cleaning of body fluids, blood, and decontamination procedures.

**Cleaning Procedures:** Blood / body fluids must be thoroughly cleaned from surfaces / objects before application of Peroxy HDOX.

**Contact Time:** Allow surface to remain wet for 5 minutes to kill HIV-1, Norovirus, [and][&] Feline Calicivirus. Use a 10 minute contact time for all other organisms claimed.

**Disposal of Infectious Material:** Blood / body fluids should be autoclaved and disposed of according to Federal, State, and local regulations for infectious waste disposal.

**For Use as a Cleaner/Sanitizer:**

Dilute 5 ounces of Peroxy HDOX concentrate per gallon of water. Thoroughly wet hard, non-porous, inanimate surface with the use-solution. The use-solution can be applied with a course spray, cloth, mop, or by soaking. For sprayer applications use a course spray device 6-8 inches from the surface. Let use-solution remain on surface for a minimum of 5 minutes, wipe clean and allow to air dry. If unusually heavy soil deposits exist, pre-clean with Peroxy HDOX (as directed for use as a cleaner) prior to sanitizing. Replace mop bucket solution daily.

**For Use as a Cleaner:**

Peroxy HDOX can be used on all surfaces not harmed by water. The use solution can be applied with a course spray, cloth, mop, soaking, or with use of the proper equipment. This product works exceptionally well as a cleaner/spotter on grouted floors walls and carpets. Recommended Dilutions are listed below:

**GREEN DILUTION**

(Light Duty)

½ oz of Concentrate per gallon Water

Spray & Wipe (Windows, Mirrors, Stainless Steel, Countertops)



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Floor Mopping  
Auto Scrubbing  
Carpet Cleaning

#### YELLOW DILUTION

(Medium Duty)

5 oz of Concentrate per gallon Water

Spray & Wipe

Bathroom Cleaning

Tile & Grout Cleaning

Odor Control (Urine, Garbage, & Room Space Spray)

Mold & Mildew Stains

Carpet Spotting & Pre-Spray

#### RED DILUTION

(Heavy Duty)

10 oz of Concentrate per gallon Water

Spray & Wipe

Bathroom Cleaning

Tile & Grout Cleaning

Odor Control (Urine, Garbage, & Room Space Spray)

Mold & Mildew Stains

Carpet Spotting & Pre-Spray

#### **For Use as a Deodorizer:**

Peroxy HDOX can be used as a deodorizer. For general deodorizing, dilute 5 oz. of [Peroxy HDOX][concentrate] per gallon of water. For high level deodorizing, dilute 10 oz. of [Peroxy HDOX][concentrate] per gallon of water. Apply to hard non-porous surface to eliminate unpleasant odors.

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{For sizes 1 gallon or less}

#### **STORAGE AND DISPOSAL**

Do not contaminate water, food or feed by storage and disposal.

Store in original container in areas inaccessible to small children. Store between 35° and 85° in dry, well ventilated area away from chemicals, direct light, heat, or open flame. Do not mix with other cleaning or disinfecting products. Keep securely closed. Offer for recycling, if available. Non-refillable container. Do not reuse or refill this container. Dispose of container according to Federal, State, and Local laws and regulations.

{For sizes over 1 gallon}

#### **STORAGE AND DISPOSAL:**

Do not contaminate water, food or feed by storage or disposal.

**PESTICIDE STORAGE:** Store in original container in areas inaccessible to small children. Store between 35° and 85° in dry, well ventilated area away from chemicals, direct light, heat, or open flame. Do not mix with other cleaning or disinfecting products. Keep securely closed.

**PESTICIDE DISPOSAL:** Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. For more information on the disposal of unused, unwanted product and the clean up of spills, contact the EPA Regional Office or the Manufacturer for guidance.

**CONTAINER DISPOSAL:** Non-refillable container. Do not reuse or refill this container. Offer for recycling [or reconditioning], if available. Dispose of container according to Federal, State, and Local laws and regulations.

#### **ENVIRONMENTAL HAZARDS**

*{for containers of 5 gallons or 50 lbs. or more}*

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System [NPDES] permit and the permitting agency has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

**[Additional Information about this product can be found at [www.earthlaboratories.com](http://www.earthlaboratories.com) or via telephone at (866) 203.0535]**

## Emerging Viral Pathogen Claims

**[PEROXY HDOX] [PRODUCT NAME] [THIS PRODUCT]** meets the criteria to make claims against certain emerging viral pathogen from the following viral categories:

- Enveloped viruses
- Large non-enveloped viruses

*For an emerging viral pathogen that is a/an... follow the directions for use for the following organisms on the label:*

For an emerging viral pathogen that is a/an...	...follow the directions for use for the following organisms on the label:
Enveloped virus	Norovirus, Feline Calicivirus
Large, Non-enveloped virus	Norovirus, Feline Calicivirus

**[PEROXY HDOX] [PRODUCT NAME] [THIS PRODUCT]** -or- this product has demonstrated effectiveness against viruses similar to **[insert name of emerging virus]** on hard, nonporous surfaces.

Therefore, **[PEROXY HDOX] [PRODUCT NAME] [THIS PRODUCT]** can be used against **[insert name of emerging virus]** when used in accordance with the directions for use against **[insert name of emerging virus]** on hard, nonporous surfaces.

Refer to the [CDC] [OIE] website at **[insert pathogen-specific website address]** for additional information.

**[Insert name of illness/outbreak]** is caused by **[insert name of emerging virus]** . **[PEROXY HDOX] [PRODUCT NAME] [THIS PRODUCT]** kills similar viruses and therefore can be used against **[insert name of emerging virus]** when used in accordance with the directions for use against **[Feline Calicivirus][Norovirus]** on hard, nonporous surfaces. Refer to the CDC -or- OIE website at **[insert pathogen-specific website address]** for additional information.